

DOCKET NO. 17501 (AP)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of
CHANG et al.

Serial No: 10/685,941

Filed: October 14, 2003

For: COMBINATION OF BRIMONIDINE
AND TIMOLOL FOR TOPICAL
OPHTHALMIC USE

Group Art Unit: 1614

Examiner: Brian S. Kwon

Confirmation No. 7685

**DECLARATION OF AN EXPERT REGARDING FACTS RELEVANT TO
PATENTABILITY (37 C.F.R. § 1.132)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PURPOSE OF DECLARATION

1. This declaration is to establish evidence of patentability of one or more claims of the above referenced application.
2. The person making this declaration is an employee of Allergan, Inc, and is an expert in following the commercial success of pharmaceutical products.
3. The purpose of this declaration is to show commercial success of the claimed product.

TESTIMONY OF COMMERCIAL SUCCESS

Summary

4. Exhibit 501A shows that total quarterly sales of COMBIGAN® topical ophthalmic solution containing 0.2% brimonidine, by weight, and 0.5% timolol by weight (hereafter COMBIGAN®) steadily and significantly increased, while the sales of brimonidine alone were roughly constant.
5. In the first six quarters after launch, total quarterly sales of COMBIGAN® brand ophthalmic solution increased from 0% to 32% relative to sales of ophthalmic products containing brimonidine as the sole active agent, which had constant sales over the same period (about \$4.2M US in the quarter of launch and \$4.4M US in the sixth quarter after launch).

6. In my expert opinion, this data is strong evidence of commercial success.

Explanation

7. This data was collected during the normal course of business. Allergan's practice is to collect sales data to track the commercial success of products after they are launched. Sales data is purchased from IMS (Intercontinental Medical Statistics). Sales are measured as pharmacy and hospital purchases from wholesalers at the ex-factory price level.
8. The combined quarterly sales for COMBIGAN® brand ophthalmic solution in the countries Brazil, Canada, and Switzerland are depicted as "COMBIGAN®" in the graph.
9. COMBIGAN® brand ophthalmic solution contains 0.2% brimonidine by weight and 0.5% timolol by weight as the sole active agents.
10. "Brimonidine alone" is the combined quarterly sales for all topical ophthalmic products containing only 0.2% brimonidine as the sole active agents in the three countries.
11. The quarter designated as "0" is the quarter in which the product was launched in the country.
12. COMBIGAN® brand ophthalmic solution was launched in September 2004 in Brazil, December 2003 in Canada, and January 2005 in Switzerland.
13. Thus, the quarter designated as "0" represents the total sales of COMBIGAN® brand ophthalmic solution for Brazil in Q3 2004, Canada in Q4 2003, and Switzerland in Q1 2005. All quarters in the graph are presented relative to this frame of reference.
14. Quarterly total sales of all topical ophthalmic products containing only brimonidine for the four quarters before launch in the three countries are depicted to the left of the launch quarter and are labeled "Quarters Before Launch."
15. Quarterly total sales of both the products containing only brimonidine and COMBIGAN® for the first five quarters after launch in the three countries are depicted to the right of the launch quarter and are labeled "Quarters After Launch."
16. Daryl M Bogard, RPh, MBA is an expert in tracking commercial success of pharmaceutical products based upon his 16 years in global pharmaceutical marketing research management.
17. He personally compiled the data presented in Exhibit 501A.

This declaration is submitted prior to final rejection.

DECLARATION

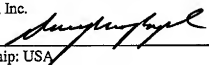
18. As a person signing below:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on Information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

19. Person who collected data

Full name: Daryl M. Bogard, RPh, MBA
Director, Global Marketing Information
Allergan, Inc.

Expert's signature: 

Date: March 6, 2007

Country of Citizenship: USA

Residence: 19 Blessing, Irvine CA 92612

EXHIBIT 501A
COMBINED SALES: BRAZIL, CANADA, SWITZERLAND

